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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,929	10/15/2003	Christopher H. Porter	355492-4151	4569
38706	7590	01/27/2006	EXAMINER	
FOLEY & LARDNER LLP 1530 PAGE MILL ROAD PALO ALTO, CA 94304			JONES, DAMERON LEVEST	
			ART UNIT	PAPER NUMBER
			1618	
DATE MAILED: 01/27/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/686,929	<b>Applicant(s)</b> PORTER ET AL.	
	<b>Examiner</b> D. L. Jones	<b>Art Unit</b> 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11/18/05; 6/7/04; 10/12/05; & 3/12/04.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 3-31 is/are pending in the application.
- 4a) Of the above claim(s) 5,8,9,14,17,18,20 and 26-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3,4,6,7,10-13,15,16,19,21-25 and 31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/18/05 &amp; 6/7/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the amendment filed 10/12/05 wherein claims 1 and 2 are canceled and claims 4-6, 11-15, 17, 18, 21, 22, 24, and 26-28 are amended. In addition, the Examiner acknowledges the amendment filed 3/12/04 wherein the specification was amended.

**Note:** Claims 3-31 are pending.

## **APPLICANT'S INVENTION**

2. The instant invention is directed to compositions and uses thereof wherein the composition comprises a non-reactive biocompatible substance, a modifier, a biocompatible liquid, and a contrast agent.

## **RESPONSE TO APPLICANT'S ELECTION**

3. Applicant's election with traverse of Group II (claims 3-25 and 31) filed 10/12/05 is acknowledged. The traversal is on the ground that searching the full scope of the instant invention would not be a burden on the Examiner. This is found non-persuasive because the inventions are separate and distinct. A search of one group would neither anticipate nor render obvious another group (see the rejections cited below). Hence, searching the full scope of the instant invention would be burdensome to the Examiner. Thus, the restriction requirement are still deemed proper and is therefore made FINAL.

**Notes:** It is duly noted that Applicant elected the species wherein the non-reactive biocompatible substance is an ethylene-vinyl alcohol copolymer; the modifier is fumed silica; the biocompatible liquid is dimethyl sulfoxide; the contrast agent is tantalum; the delivery device is a catheter; the thickening agent is poly(methyl

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methacrylate); the plasticizer is a citrate ester; the radioactive agent is 125iodine; the surfactant is Tween 20; and the medicament is a thrombotic agent. The search was not further expanded because prior art was found which could be used to reject the instant invention. Claims 3, 4, 6, 7, 10-13, 15, 16, 19, 21-25, and 31 read on the elected species.

#### **WITHDRAWN CLAIMS**

4. Claims 5, 8, 9, 14, 17, 18, 20, and 26-30 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

#### **DOUBLE PATENTING REJECTIONS**

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 3, 4, 6, 7, 10-13, 15, 16, and 21-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/687,545. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to compositions comprising a polymeric material and a theological modifier. The claims differ in that the instant invention also requires the present of a biocompatible liquid and a contrast agent. It would be obvious to one of ordinary skill in the art to incorporate a biocompatible liquid (i.e., water) and a contrast agent because the claims of 10/687,545 allow for additional components in the composition and disclose that a contrast agent (see claim 9) is a further component of their composition. In addition, 10/687,545 discloses that other components such as thickening agents,

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plasticizers, radioactive agents, and surfactants may be present which all may be encompassed by under the phrase 'biocompatible liquid' as set forth in the instant invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### 103 REJECTIONS

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 3, 4, 6, 7, 10-13, 15, 16, 19, 21, 22, 24, 25, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patterson et al (US 2004/0224864).

**Patterson et al** disclose sterilize embolic compositions that may be administered to a subject via a catheter and may comprise a contrast agent, prepolymer, and optionally thickeners and/or theological modifiers for diagnostic and therapeutic purposes (see entire document, especially, abstract; page 2, paragraph [0030]; and pages 2-3, bridging paragraph). In another embodiment, the composition comprises (1) a biocompatible polymer; (2) a biocompatible solvent; (3) optionally, a biocompatible water insoluble contrast agent; and (4) a fumed silica or other hydroxyl containing theological modifier (page 3, paragraph [0048]). The method of embolizing a vascular site in a mammal comprises delivering the composition via a catheter (page 3,

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paragraph [0051]). Possible biocompatible contrast agents include water insoluble contrast agents such as tantalum, tantalum oxide, gold, tungsten, platinum, and barium sulfate. Likewise, water soluble contrast agents such as lipidol and metrizamide may be utilized (page 8, paragraphs [0129] and [0130]). A possible biodegradable polymer that may be utilized includes polymethyl methacrylate (pages 8-9, bridging paragraph). Non-biodegradable biocompatible polymers include ethylene vinyl alcohol copolymers, a preferred polymer (page 9, paragraphs [0133] and [0135]). A possible biocompatible solvent is dimethylsulfoxide (DMSO) (page 9, paragraph [0139]). In addition, surfactants (i.e., Tween) and biocompatible plasticizers (i.e., citrate derivatives) may be present (page 10, paragraphs [0147] and [0148]). On page 11, paragraph [0173], Patterson et al disclose that other combinations besides silica, ethylene vinyl alcohol copolymer, DMSO, and tantalum may be utilized. On page 12, paragraph [0185], a combination comprising fumed silica and ethylene vinyl alcohol copolymer is disclosed. In Example 2, page 18, a composition comprising ethylene vinyl alcohol copolymer, DMSO, tantalum, and silica is disclosed. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to generate a composition comprising a non-reactive biocompatible substance, a theologically modified, a biocompatible liquid, and a contrast agent because both Applicant and Patterson et al disclose compositions comprising such components.

#### **COMMENTS/NOTES**

9. Applicant is not entitled to the date of the provisional application, 60/418,251 filed 10/15/02, because one could not locate each component as set forth in the instant

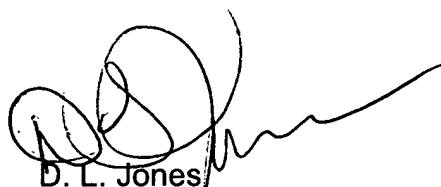
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invention. If Applicant is in disagreement with the Examiner, it is respectfully requested that Applicant point to page(s) and line number(s) wherein support may be found for the instant invention.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. L. Jones  
Primary Examiner  
Art Unit 1618

January 23, 2006